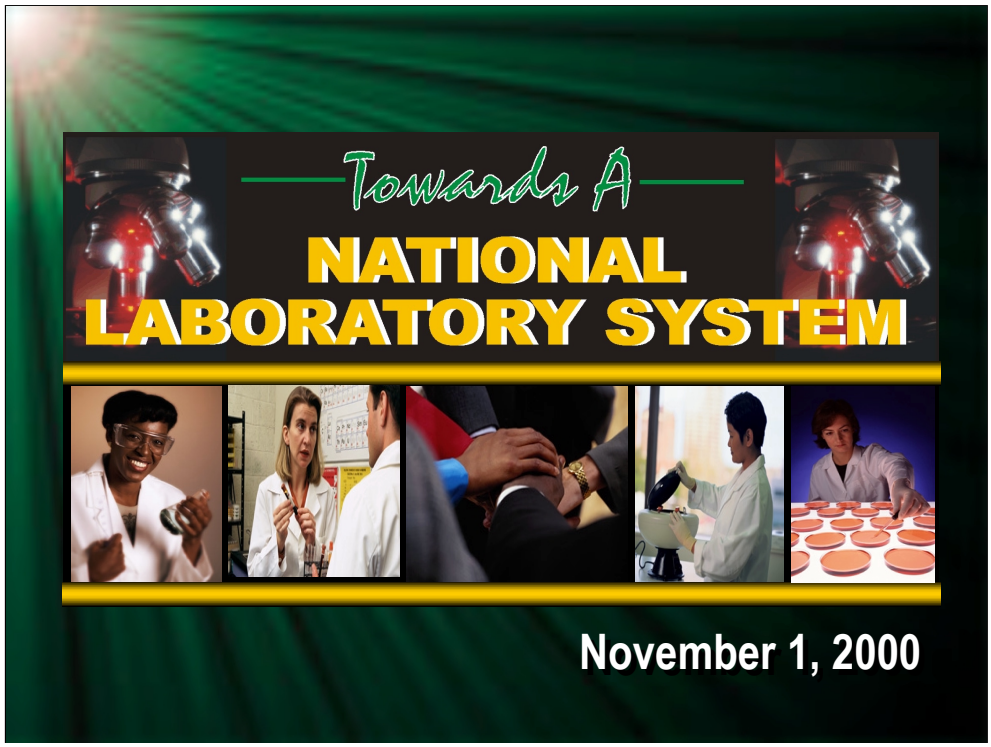
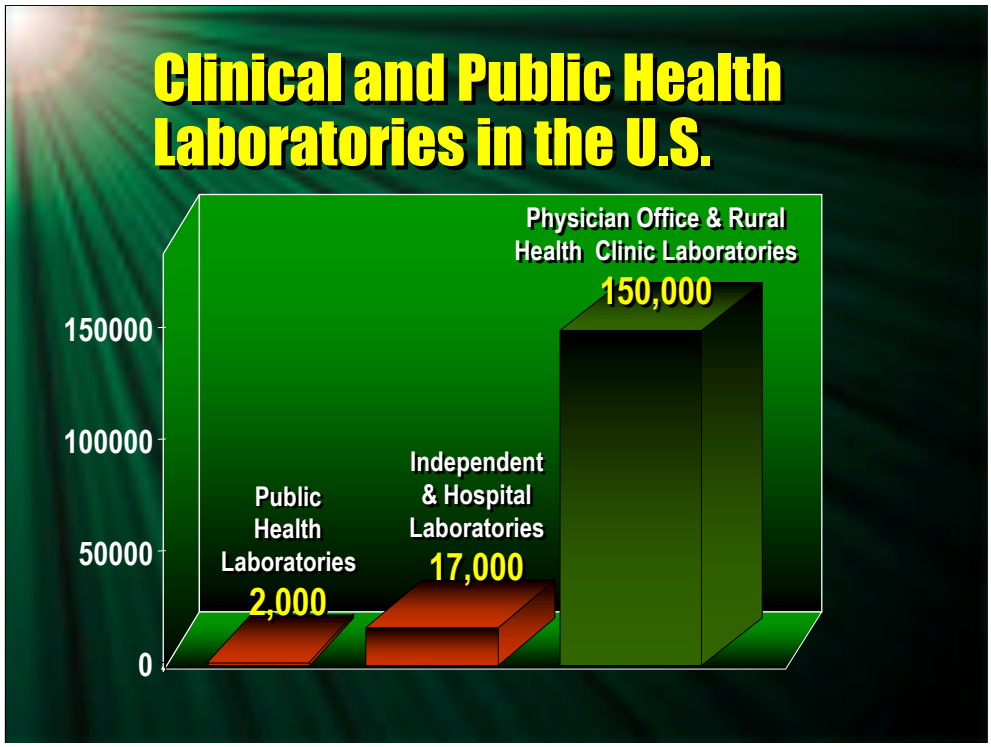


Slide 1:

The National Laboratory System is all about people. It is about bringing together laboratorians with different perspectives and working together to assure the availability of consistent laboratory capacity for public health across the nation.

Slide 2:

Initial concept development and planning for the National Laboratory System occurred within the NLS strategic planning team at the Division of Laboratory Systems.



Slide 3:

In order to assure adequate and consistent capacity for testing of public health importance we must focus on the laboratories where this testing occurs. Much of this testing is either completed or referred by hospital and independent laboratories. Equally important is the testing conducted by the 50 State public health laboratories, Territorial laboratories and the large number of small public health laboratories serving regions, counties and municipalities. It is characteristic of the problem that we do not have an accurate estimate of either the number of laboratories in each category or the types and volumes of important public health testing that they perform.

Public health laboratories come in a wide variety of “flavors’ related to the wide variability in populations served, available resources, endemic public health concerns, mandates to privatize some functions and/or opportunities to affiliate with academic centers.

Slide 4:

Public Health laboratories are focused on and play a number of extremely important roles in protecting the Nation's health, including those identified in the Association of Public Health Laboratories (APHL), 1999 white paper - *Core Functions and Capabilities.*

Clinical laboratories also play important roles in protecting the Nation's health, but are more oriented toward cost conscious individual patient care.

These cultures are very different and they sometimes result in either miscommunication or non-communication.


What do public health labs do?
APHL Core Functions Statement, 1999
Policy Development
Emergency Response
Public Health Related Research
Training and Education
Partnerships and Communication

Slide 5:

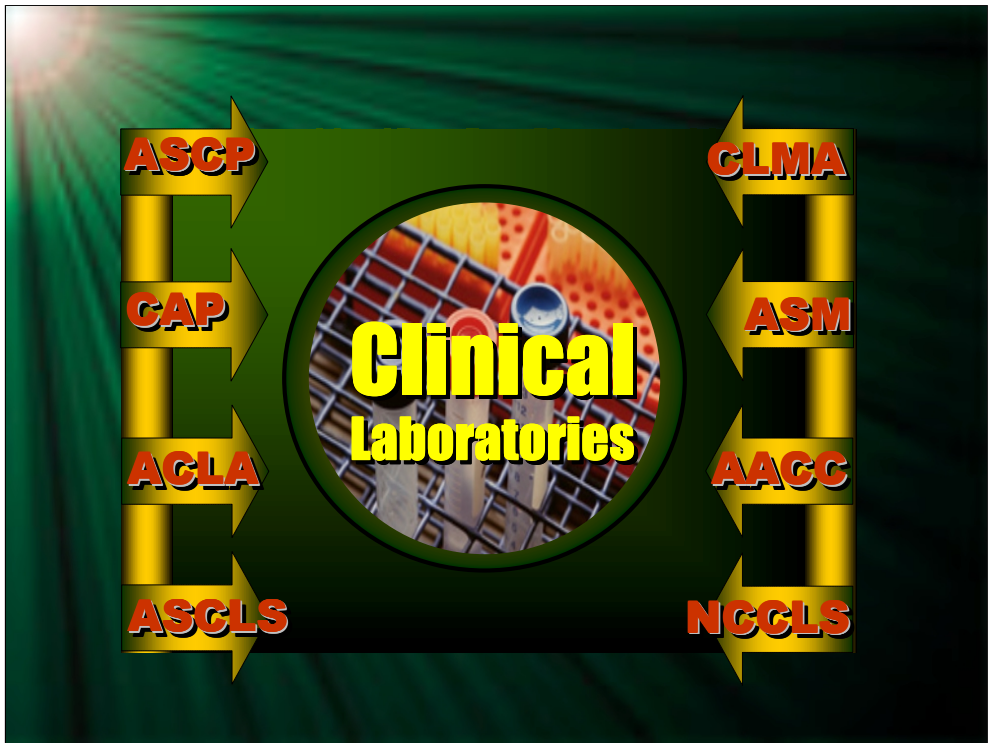
Slide 6:

There are other differences as well. Consider that most public health testing occurs within one of three principal domains, Federal Agencies, State and local Health Departments and private sector clinical laboratories.

Disease surveillance and testing of public health significance occurs at Centers for Disease Control and Prevention (CDC). Other federal agencies including the Health Care Finance Administration (HCFA) and Food and Drug Administration (FDA) play important roles in determining how all clinical testing is conducted in the U.S.

Slide 7:

State and local public health departments include such stake holders as the Council of State and Territorial Epidemiologists (CSTE), National Association of County & City Health Officials (NACCHO), Association of State and Territorial Health Officers (ASTHO) and the Association of Public Health Laboratories (APHL).



Slide 8:

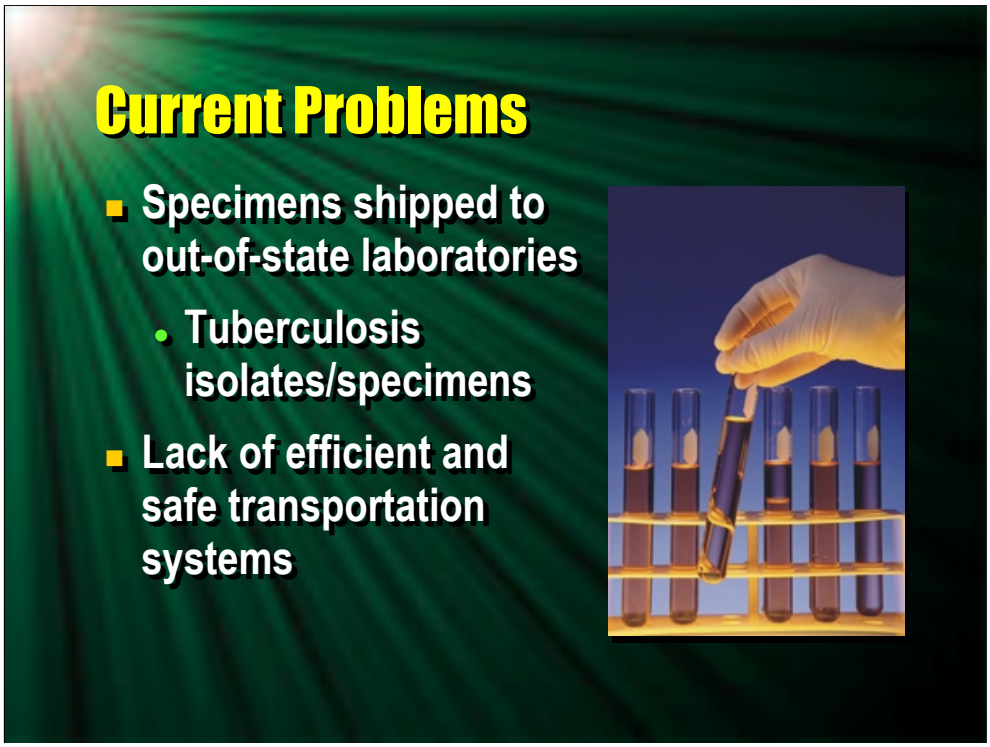
Even more diverse are the interests represented in the third and most fundamental domain, clinical laboratories. Here various organizations represent the interests of clinical pathologists, medical technologists, laboratory scientists, large reference laboratories, laboratory managers, managed care and professional organizations.

The National Committee for Clinical Laboratory Standards (NCCLS) works to bring all of interest represented by these 3 domains (as well as those of in vitro diagnostics manufacturers) together to produce and foster workable guidelines.

Slide 9:

The NLS will serve to bring the diverse interests of these groups together to facilitate communication and coordination of testing important to public health so as to provide appropriate testing capacity and timely testing/reporting.

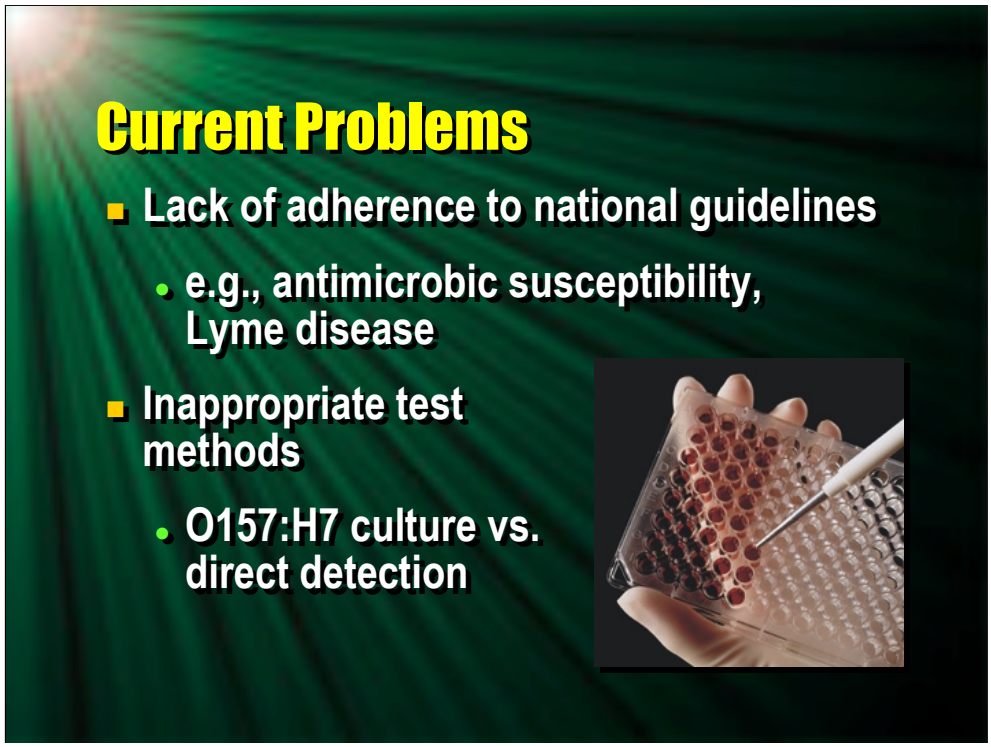
The NLS will also foster the appropriate sharing of specimens and information including patient/population data, standards and relevant continuing education materials.



Slide 10:

A common problem facing public health is the loss of epidemiologic data from specimens tested in out-of-state laboratories. Because no permanent culture is retained, it is often impossible to perform molecular fingerprinting.

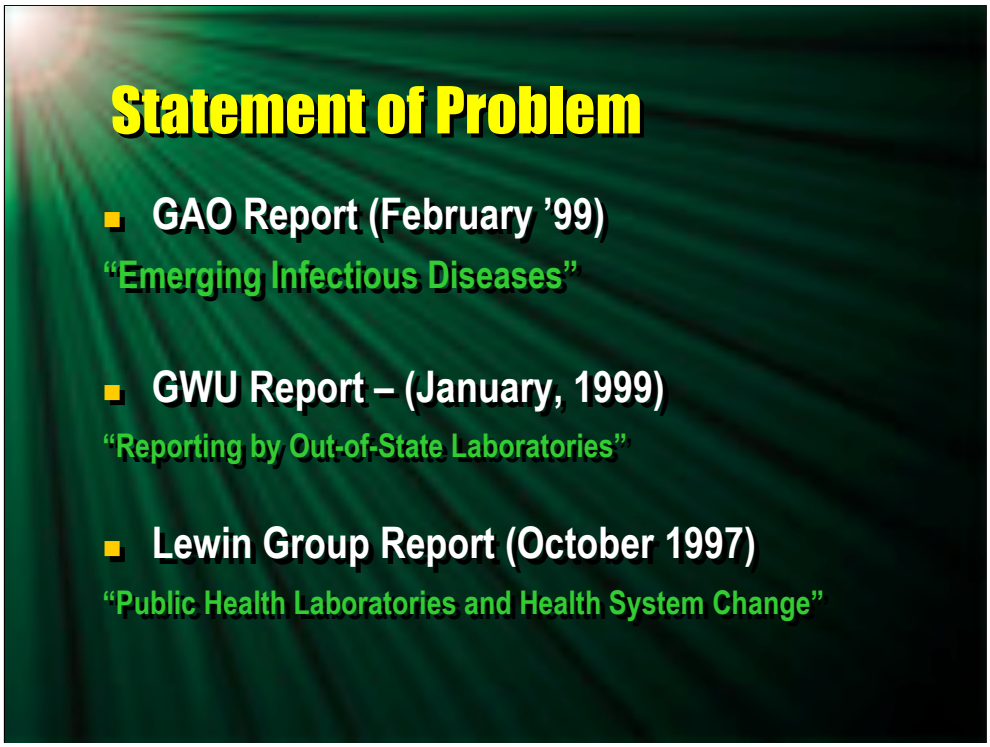
Another problem is the lack of safe and expedient means for transporting isolates.



Slide 11:

All to often, clear guidelines for testing exist yet they are not followed either due to ignorance, indifference or limited resources.

Commonly, because clinical needs focus on individual rather than population health, testing falls short of providing all the data needed for protecting the health of the community. For example, patients with with an enteric infection may test positively for Shiga toxin and be treated appropriately for the clinical situation, but because no culture was obtained it is impossible to fully identify the pathogen or source of infection. This hampers efforts to identify potential outbreaks and alert the community. This example illustrates a lack of communication or coordination between public health laboratories and clinical laboratories resulting in sub-optimal testing.



Slide 12:

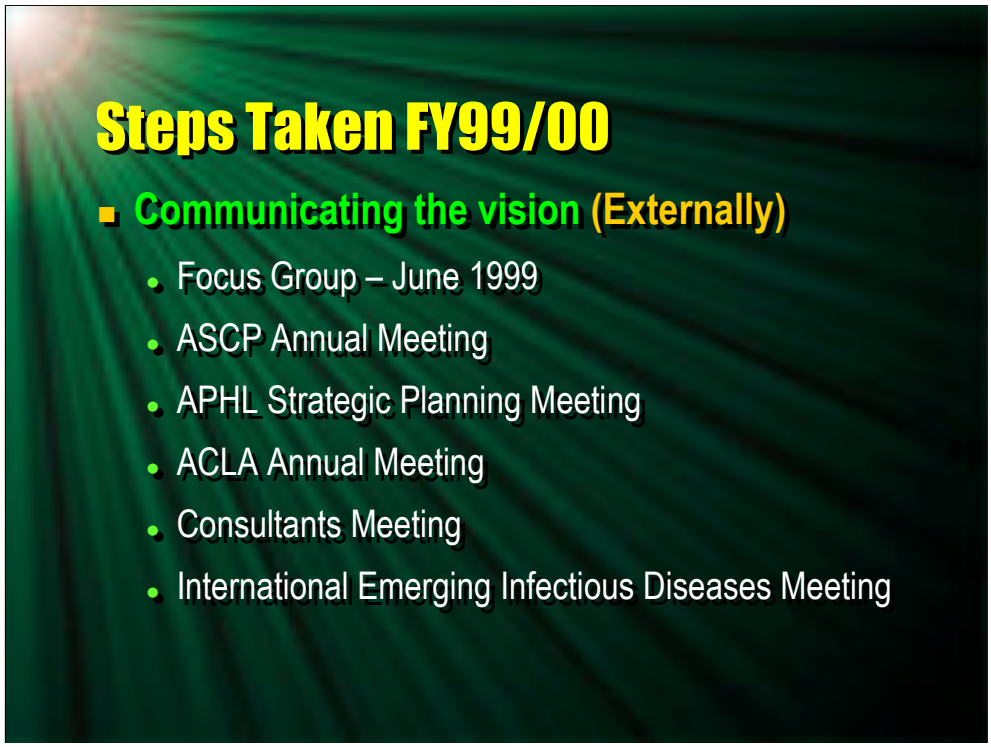
There have been several exhaustive reports addressing the problems confronting public health laboratories including the Lewin report which was fairly blunt concerning the need for leadership from the public sector:

"Our results also show that there has been little proactive leadership from the public sector in shaping the laboratory delivery system. With a few notable exceptions, lab directors, state decision makers, and the federal government have done little to strengthen the PHL infrastructure. There is no single and clear locus of responsibility for such matters within the CDC or elsewhere at HHS. ...the entire system needs to be reviewed carefully..."

The stars seem to be coming into alignment for creation of a NLS Perhaps that is a result of these studies, as well as lay publications, such as "Betrayal of Trust."

Slide 13:

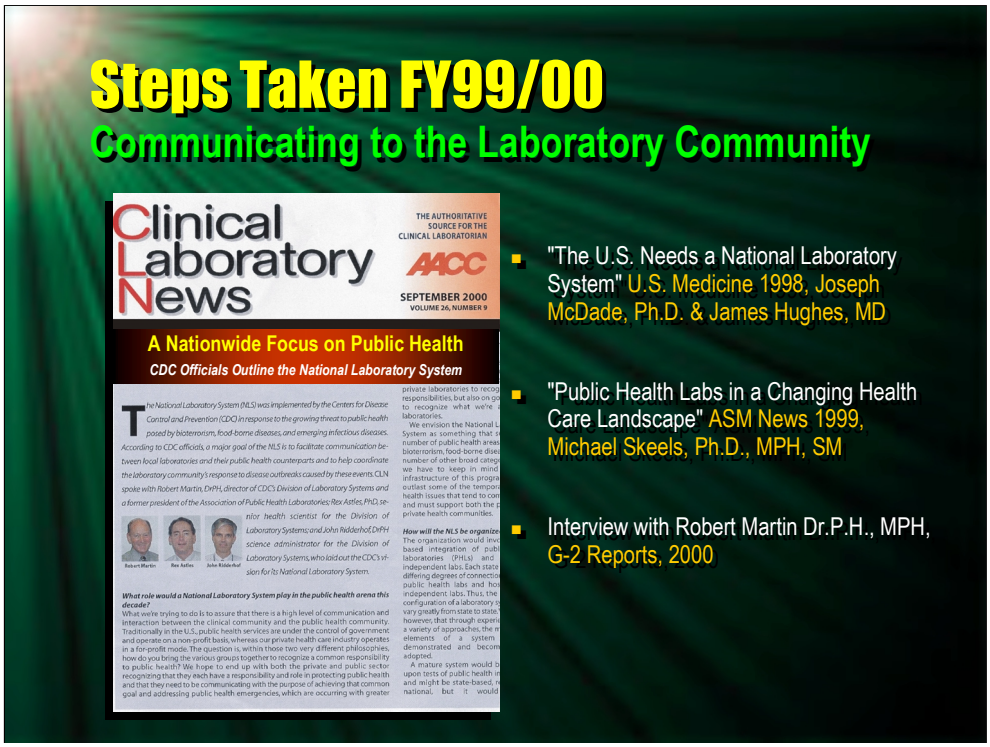
The Division of Laboratory Systems (DLS) has been working to promote the NLS internally and has met with various internal stakeholders, including the Health Information Systems Surveillance Board, National Center for Environmental Health and Bioterrorism Planning and Response Program.



Slide 14:

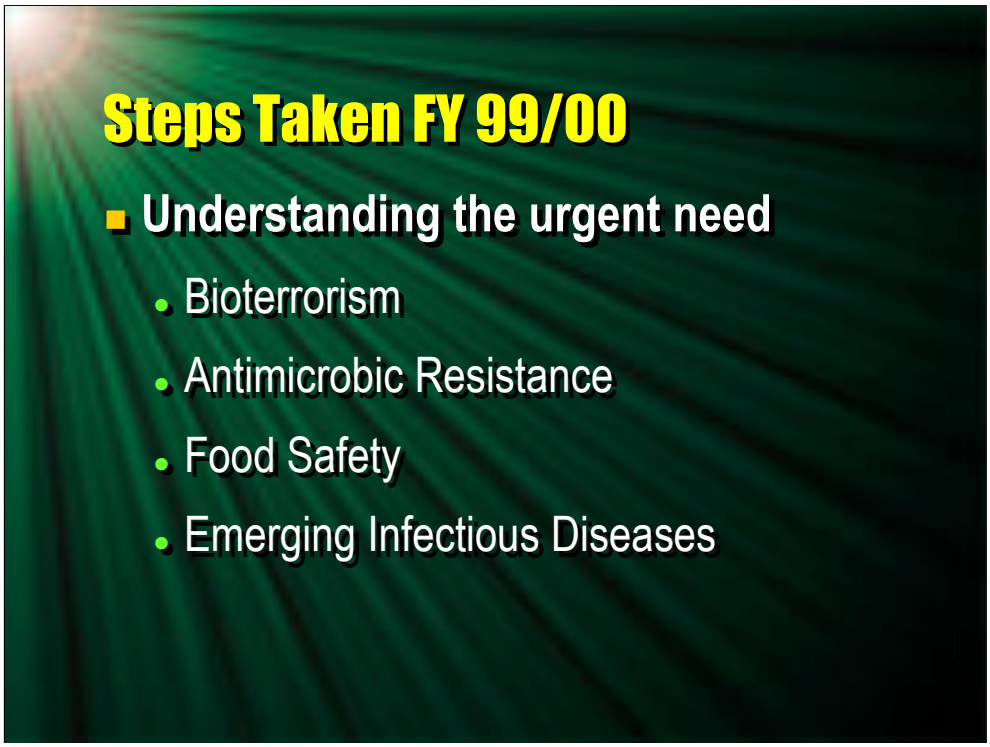
DLS has also focused efforts upon external organizations such as American Society of Clinical Pathologists (ASCP), Association of Public Health Laboratories (APHL) , American Clinical Laboratory Association (ACLA), Association of State and Territorial Health Officers (ASTHO), Council of State and Territorial Epidemiologists (CSTE), American Society for Clinical Laboratory Science (ASCLS) and others.

In addition, DLS has convened a focus group and consultant's meeting that pulled together these interests plus important stakeholders from CDC, including the National Center for Infectious Diseases (NCID), Bioterrorism Preparedness and Response Program (BPRP) and Foodborne Illness groups.



Slide 15:

The concept of the NLS has been publicized in trade publication such as Clinical Laboratory News (CLN) and the American Society for Microbiology (ASM) News. The concept has also been presented to a large audience at a recent a G-2 meeting. Dr. Joe McDade and Dr. Jim Hughes of the National Center for Infectious Diseases (NCID) have called for a national laboratory system in an article in U.S. Medicine.



Slide 16:

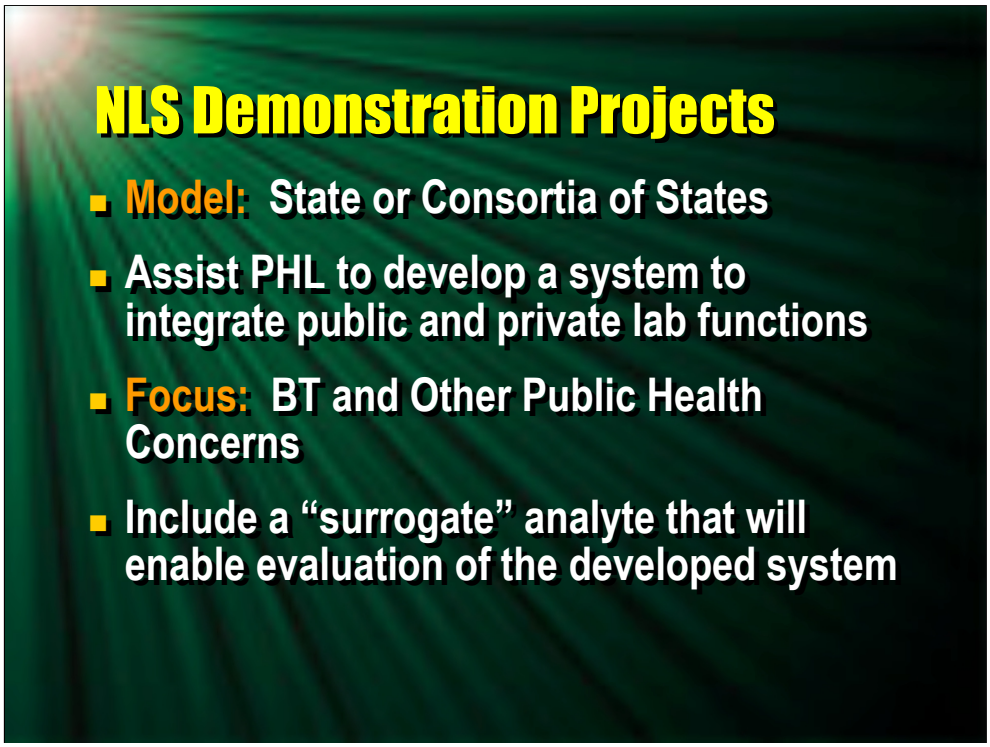
Throughout the planning for the NLS, the Division of Laboratory Systems has strived to understand needs of the various programs addressing urgent public health problems such as bioterrorism, antimicrobial resistance, food safety and emerging infectious disease.

We will continue to interact with these groups and demonstrate how a systematic approach to laboratory issues can benefit their programmatic efforts.

Slide 17:

DLS has partnered with APHL to develop a solicitation, funded by CDC, for participation by state health labs in creation of novel systematic laboratory systems. We anticipate this demonstration project will include a consortium of states that will develop a system that crosses state boundaries. The deadline for applications is December 8, 2000 and awards will be made in early 2001.

We also have a similar cooperative agreement in place with Dr. Jon Counts through the University of Washington School of Public Health and the Foundation for Health Care Quality.



Slide 18:

The APHL demonstration project will place a laboratory program advisor in the recipient state public health laboratory. This scientist will work with the state laboratory director to develop a system that will begin to integrate public and private laboratory functions by increasing communication and coordination of efforts.

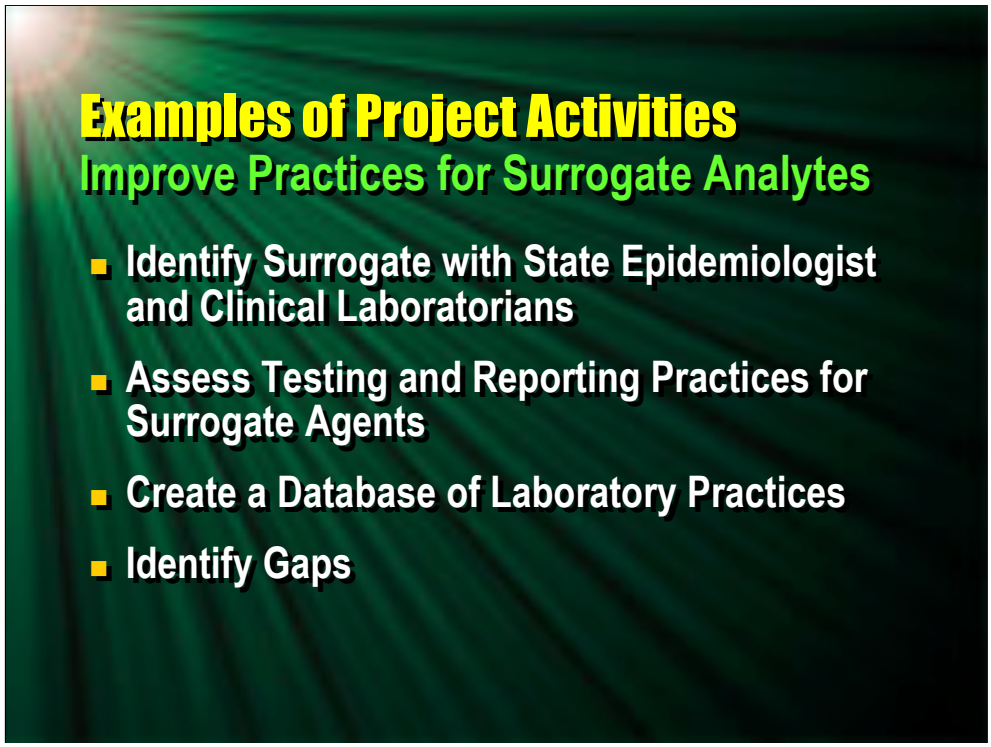
We hope to encourage the development of systematic components that will improve the detection or response to a bioterrorism event. Recognizing that BT events are rare and unpredictable, we included a provision for a "surrogate" analyte to allow us to measure a change in outcome to a public health threat. Surrogates should be selected with the help of the state epidemiologist and should be public health threats that occur sporadically, but with sufficient frequency to allow assessment of baseline performance and and a change in outcomes post-intervention.

Slide 19:

The APHL demonstration project - and any project to systematically promote integration of public and private functions - should focus upon 4 key areas: 1) partnership building, 2) assessment, 3) training and 4) standards. Partners might include local and state public health laboratories, hospital and independent laboratories, health maintenance organizations (HMO), and possibly federal agencies such as HCFA. Assessment should include the kinds of laboratories performing testing of public health significance, the number of public health laboratories in the area of interest, the kinds of testing in these laboratories, adherence to standards and the characteristics of the personnel managing the laboratories and performing the testing. In the case of the APHL demonstration project, it should assess baseline performance with a surrogate and a change in function after intervention. Training of laboratorians and managers should be included. Finally, where standards exist but are not followed there should be promulgation of the existing standards; in other cases it may be necessary to create standards.

Slide 20:

As yet it is uncertain what kinds of system components will be suggested by the State applicants for the APHL demonstration projects; there are many opportunities, as shown in this slide and the next. All applications should include a strong educational component for BT agents.

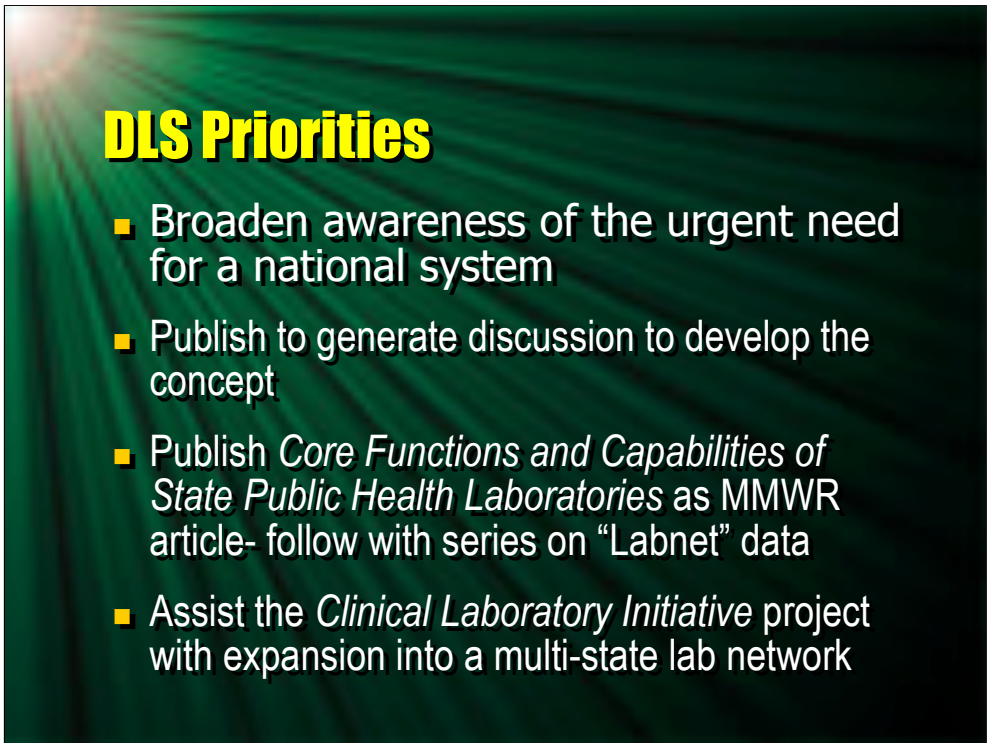


Slide 21:

For surrogate agents, we expect proposals to include elements of assessment, identification of gaps, intervention and re-assessment during the two-year term of the project.

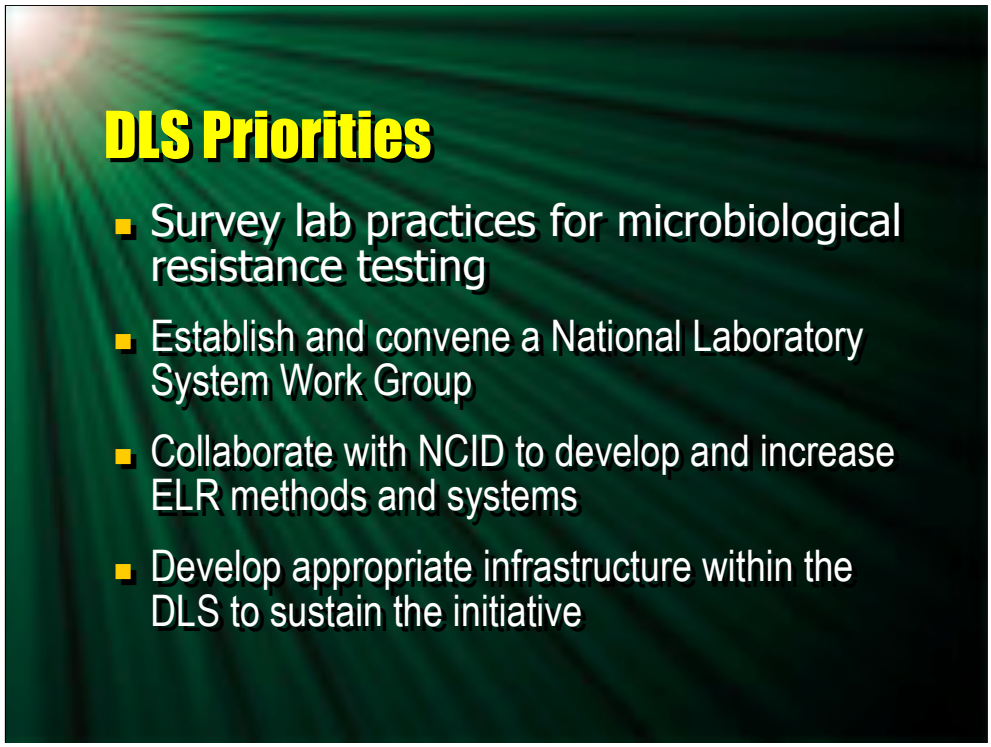

Examples of Project Activities
Improve Practices for Surrogate Analytes
Promote Standards and Training
Evaluate and Reassess Testing Practices to Determine Effectiveness of Demonstration Project

Slide 22:



Slide 23:

DLS priorities for the future include broadening the awareness of the urgent need for a NLS using all available media. We plan to publish in peer reviewed journals as well as trade publications to generate further input and discussions to better develop the NLS concept. We will publish an article in the Morbidity and Mortality Weekly Report (MMWR) announcing the APHL white paper on core functions and capabilities. We will assist Dr. Counts to expand the WA State Clinical Lab Initiative to adjacent states.



Slide 24:

We hope to collaborate with NCID to survey current lab practices in resistance testing. We will also collaborate with NCID to develop and increase electronic laboratory reporting methods and systems. We will establish a work group to advise our development of the NLS. We also expect to continue to develop infrastructure in DLS to support these activities.

Slide 25:

The long term goal is protecting the health of our communities by enhancing the communication and coordination of public and private sector laboratories to assure that the Nation has the appropriate testing capacity to respond to challenges of public health significance.